

AMENDMENTS TO THE CLAIMS

1. (Currently amended) A stable and soluble Ppharmaceutical composition characterized by comprising:

- (a) a therapeutic amount of the protease inhibitor [5S-(5R\*,8R\*,10R\*,11R\*)]-10-hydroxy-2-methyl-5-(1-methylethyl)-1-[2-(1-methylethyl)-4-thiazolyl]-3,6-dioxo-8,11-bis(phenylmethyl)-2,4,7,12-tetraazatridecan-13-oic acid 5-thiazolylmethyl ester (ritonavir) employed in an amount ranging from 1.0% to 50% in weight of the final composition;
- (b) a mixture of alcoholic solvent and alcoholic co-solvent from of C<sub>2</sub>-C<sub>4</sub> which are employed in total amount ranging from 10% to 30% in weight of the final composition;
- (c) a mixture of C<sub>8</sub>-C<sub>10</sub> medium chain mono/diglycerides of C<sub>8</sub>-C<sub>10</sub> employed in an amount ranging from 20% to 70% in weight of the final composition;
- (d) a pharmaceutical suitable surfactant employed in an amount ranging from 0.1% to 20% in weight of the final composition;
- (e) an antioxidant employed in an amount ranging from 0.001% to 2.0% in weight of the final composition.

2. (Currently amended) The Ppharmaceutical composition in accordance with claim 1, characterized by which optionally comprising further comprises:

- (a1) an emulsion-stabilizer-stabilizing agent employed in an amount ranging up to 60% in weight of the final composition;
- (b1) a polarity corrector agent employed in an amount up to 0.5% in weight of the final composition.

3. (Canceled)

4. (Canceled)

5. (Canceled)

6. (Currently amended) ~~The~~ Pharmaceutical composition in accordance with claim ~~5~~ 1,  
~~characterized by wherein~~ the alcoholic solvent is used in a concentration ranging from 5.0%  
to 15% in weight of the final composition.

7. (Canceled)

8. (Currently amended) ~~The~~ Pharmaceutical composition in accordance with claim ~~7~~ 1,  
~~characterized by wherein~~ the alcoholic co-solvent is used in a concentration ranging from 5.0  
to 15% in weight of the final composition.

9. (Canceled)

10. (Canceled)

11. (Canceled)

12. (Canceled)

13. (Canceled)

14. (Canceled)

15. (Currently amended) ~~The~~ Pharmaceutical composition in accordance with claim 1,  
~~characterized by wherein~~ the alcoholic solvent is ethanol and the alcoholic co-solvent is  
propylene glycol.

16. (Currently amended) ~~The~~ Pharmaceutical composition in accordance with claim 1,  
~~characterized by wherein~~ the surfactant is polyethoxylated castor oil 35, and/or hydrogenated  
polyethoxylated castor oil 40, and/or polysorbates 20, 40, 60 or 80.

17. (Currently amended) ~~The~~ Pharmaceutical composition in accordance with claim 1, ~~characterized by~~ wherein the antioxidant is butylated hydroxy toluene and/or alpha-tocopherol.

18. (Canceled)

19. (Currently amended) ~~The~~ Pharmaceutical composition in accordance with claim 1 ~~or~~ 2, ~~characterized by~~ wherein the emulsion-stabilizing agent is polyethylene glycol 400 (PEG 400).

20. (Canceled)

21. (Currently amended) ~~The~~ Pharmaceutical composition in accordance with claim 1 ~~or~~ 2, ~~characterized by~~ wherein the polarity corrector agent is citric acid and/or ascorbic acid.

22. (Currently amended) ~~The~~ Pharmaceutical composition in accordance with ~~any one of~~ claims 1-21, ~~characterized by being~~ which is employed for oral administration as an oral solution, hard gelatin capsules and/or soft gelatin capsules.

23. (Currently amended) ~~The~~ Pharmaceutical composition in accordance with claim 22, ~~characterized by being~~ which is employed for oral administration as soft gelatin capsules.

24. (Currently amended) ~~The~~ Pharmaceutical composition in accordance with ~~any one of~~ claims 1-21, ~~characterized by being~~ which is employed in the treatment of viral infections;

25. (Currently amended) ~~The~~ Pharmaceutical compositions in accordance with ~~any one of~~ claims 1-21, ~~characterized by being~~ which is employed in medicine or veterinary;

26. (Currently amended) Process for preparing the soluble, stable, and concentrated pharmaceutical compositions of ~~[5S-(5R\*, 8R\*, 10R\*, 11R\*)]-10-hydroxy-2-methyl-5-(1-methylethyl)-1-[2-(1-methylethyl)-4-thiazolyl]-3,6-dioxo-8,11-bis(phenylmethyl)-2,4,7,12-tetraazatridecan-13-oic acid 5-thiazolylmethyl ester (ritonavir)]~~, of claim 1 comprising the following steps:

(a2) dissolving ~~[5S-(5R\*, 8R\*, 10R\*, 11R\*)]-10-hydroxy-2-methyl-5-(1-methylethyl)-1-[2-(1-methylethyl)-4-thiazolyl]-3,6-dioxo-8,11-bis(phenylmethyl)-2,4,7,12-tetraazatridecan-13-oic acid 5-thiazolylmethyl ester (ritonavir)]~~, in a sufficient amount of an alcoholic solvent of C<sub>2</sub>-C<sub>4</sub>, under controlled temperature to make a first mixture;

(b2) eliminating solid particles from said first mixture by filtration;

(c2) evaporating the alcoholic solvent from said filtered first mixture, under reduced pressure at low temperature to about half of its initial concentration;

(d2) adding to said filtered and concentrated first mixture an alcoholic co-solvent, a medium chain mono/diglycerides mixture, an antioxidant, an emulsion-stabilizing agent and a polarity corrector to make a second mixture in the appropriate amounts for the composition;

(e2) removing the alcoholic solvent of step (a2) from said second mixture by distilling under reduced pressure until the remaining quantity is the desired quantity in the composition;

(f2) adding to said distilled second mixture the a surfactant under continuous stirring, and keeping stirring until said surfactant added to said distilled second complete mixture becomes a clear solution, thereby obtaining a soluble stable and concentrated ritonavir pharmaceutical composition;- and

(g2) correcting the composition-final weight of said pharmaceutical composition by adding the alcoholic solvent employed in the initial dissolution of ritonavir step (a2), if necessary.

27. (Currently amended) ~~The P~~process in accordance with claim 26, ~~characterized by~~ wherein the alcoholic solvent used in (a2) is ethanol.
28. (Currently amended) ~~The P~~process in accordance with claim 26, ~~characterized by~~ wherein the step (a2) is conducted in a temperature ranging from 30° C to 45°C.
29. (Currently amended) ~~The P~~process in accordance with claim 26, ~~characterized by~~ wherein the step (c2) is conducted at a maximum temperature of 40°C.
30. (Currently amended) ~~The P~~process in accordance with claim 26, ~~characterized by~~ wherein the co-solvent employed in step (d2) is propylene glycol.
31. (Currently amended) ~~The P~~process in accordance with claim 26, ~~characterized by~~ wherein the medium chain mono/diglycerides employed in step (d2) is a mixture of C<sub>8</sub>-C<sub>10</sub> medium chain mono/diglycerides ~~of C<sub>8</sub>-C<sub>10</sub>~~.
32. (Currently amended) ~~The P~~process in accordance with claim 26, ~~characterized by~~ wherein the antioxidant employed in step (d2) is butylated hydroxy toluene or alpha-tocopherol.
33. (Currently amended) ~~The P~~process in accordance with claim 26, ~~characterized by~~ wherein the emulsion-stabilizing agent employed in step (d2) is polyethylene glycol 400 (PEG 400).
34. (Currently amended) ~~The P~~process in accordance with claim 26, ~~characterized by~~ wherein the polarity corrector is citric acid or ascorbic acid.

35. **(Currently amended)** ~~The~~ Process in accordance with claim 26, ~~characterized by~~  
wherein the surfactant is polyethoxylated castor oil 35, and/or polyethoxylated hydrogenated  
castor oil 40, and/or polysorbates 20, 40, 60 or 80.

36. **(Canceled)**